

§ 476.121

(7) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers;

(8) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.121 Optional disclosure of non-confidential information.

A PRO may, on its own initiative, subject to the notification requirements in § 476.105, furnish the information available under § 476.120 to any person, agency, or organization.

DISCLOSURE OF CONFIDENTIAL INFORMATION

§ 476.130 Disclosure to the Department.

Except as limited by §§ 476.139(a) and 476.140 of this subpart, PROs must disclose all information requested by the Department to it in the manner and form required.

§ 476.131 Access to medical records for the monitoring of PROs.

HCFA or any person, organization or agency authorized by the Department or Federal statute to monitor a PRO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

42 CFR Ch. IV (10-1-99 Edition)

§ 476.132 Disclosure of information about patients.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, a PRO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient's representative if—

(i) The patient or the patient's representative requests the information in writing;

(ii) The request by a patient's representative includes the designation, by the patient, of the representative; and

(iii) All other patient and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the PRO provides the requested information. If the attending practitioner states that the released information could harm the patient, the PRO must act in accordance with paragraph (c)(2) of this section. The PRO must make disclosure to the patient or patient's representative within 30 calendar days of receipt of the request.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the PRO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

(c) *Manner of disclosure.* (1) The PRO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the PRO must

disclose the information to the patient's designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the PRO must disclose the information to a person whom the PRO determines is responsible for the patient.

The PRO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the PRO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the PRO must make a determination based on other reliable information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.133 Disclosure of information about practitioners, reviewers and institutions.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) *Disclosure to the identified individual or institution.* A PRO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) *Disclosure to others.* (i) A PRO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) In accordance with section 1160 of the Act, a PRO must disclose information that displays practice or performance patterns of a practitioner or institution in accordance with the procedures for disclosures specified in §§ 476.137 and 476.138 to—

(A) Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs, and

(B) Federal and State agencies that are responsible for licensing and certification of practitioners and providers.

(iii) A PRO may disclose to any person, agency or organization, information on a particular practitioner or re-

viewer with the consent of that practitioner or reviewer provided that the information does not identify other individuals.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the PRO must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

[50 FR 15359, Apr. 17, 1985, as amended at 52 FR 37458, Oct. 7, 1987; 52 FR 47004, Dec. 11, 1987]

§ 476.134 Verification and amendment of PRO information.

(a) A PRO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the PRO.

(b) If the PRO agrees with the request for amendment, the PRO must correct the information in its possession. If the information being amended has already been disclosed, the PRO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the PRO disagrees with the request for amendment, a notation of the request, reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

[50 FR 15358, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 476.135 Disclosure necessary to perform review responsibilities.

(a) *Disclosure to conduct review.* The PRO must disclose or arrange for disclosure of information to individuals and institutions within the PRO review